VWG
Victory Wholesale Grocers

July 7, 2003

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Via Facsimile (202) 395-6974 Attn: Stuart Shapiro
And Federal Express

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 02N-0277
Section 306 (Recordkeeping)

Dear Sir or Madam:

Victory Wholesale Grocers ("Victory") hereby submits these comments regarding the FDA's May 9, 2003 proposed rule concerning recordkeeping requirements (Section 306) promulgated under the Public Health Security and Bioterrorism Act of 2002 ("Act")[1]. Victory is concerned that the proposed rule will impose new burdens on smaller wholesale food distributors that are not justified by the suggested public benefits. The proposed rule would require the establishment and maintenance of certain records that would permit the identification of the immediate previous source and the immediate subsequent recipient of food by, among other means, lot code. The stated objective of the rule is to facilitate the ability of the FDA to efficiently investigate food-related emergencies. The premise behind the proposed rule is that the new records will increase the ability of law enforcement to successfully trace contaminated food back to the source of the contamination, including, potentially, terrorists who may attempt to tamper with the U.S. food supply. The rules are supposed to provide flexibility with minimum burdens on those industry participants who will be subject to the new requirements. For reasons outlined in detail below, both aspects of this premise are grossly flawed. Instead, the proposed rule imposes requirements that are unnecessary to the Agency's proper performance of its functions (and are not required by the underlying statutory authority), and creates substantial new burdens and costs on the food distribution system.

First, it may be helpful to know a little about Victory's business. Victory, established in 1978, is a privately held national wholesale distributor of grocery; health and beauty care and general merchandise goods. Victory's customers range from the nation's largest wholesale and self-distributing retail grocery, drugstores and mass merchandise chains to small mom and pop grocery stores and drugstores. Victory employs approximately 250 associates in 12 states. Victory operates six distribution facilities throughout the country and on the island of Puerto Rico. In addition, at any

[1] 68 Fed. Reg. 25188.

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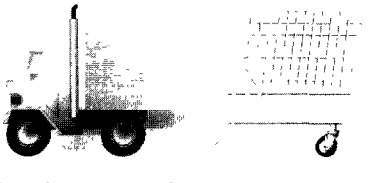

given time Victory may have product in dozens of public warehouses throughout the country being cross-docked or awaiting shipment. Victory transports goods it buys and sells through common carriers (truck, rail and ship). Victory's presence in the marketplace increases competition, improves overall market efficiency and benefits retailers and consumers by providing access to lower priced goods.

Victory supports the FDA's laudable objectives in promulgating the rule, however, the rule, if implemented as proposed, would seriously threaten Victory and other small food distributors' businesses. In Section VI of these comments, Victory reports the results of a time/cost study that it conducted at one of its facilities to determine the actual costs of complying with the proposed rule. As explained therein, Victory's own trial run indicates that the rule could cost it as much as $10,000,000 annually per facility, plus additional costs to implement changes in the Company's computer systems. In Section VII hereto, Victory suggests a number of alternative solutions to address the contamination threat.

I. The Problem with The Lot Tracking Requirement

Victory objects to the portions of the proposed regulations that would require it to establish and maintain records which reflect "[t] he lot or code number or other identifier of the food (to the extent this information exists)" and to any other portions of the proposed regulations that are intended to require wholesalers/distributors to establish and maintain records that track each specific food from its immediate previous source to its immediate subsequent recipient. For brevity, Victory will refer only to the lot or code number requirement in the balance of its comments, but these references, and Victory's objection, should be understood to also include any other requirement that Victory's records identify, for each particular shipper[2] or pallet of food shipped to a customer, the company from whom Victory received that specific shipper/pallet, and correspondingly for each particular shipper or pallet of food received by Victory, the company or companies to whom Victory shipped that shipper/pallet.

The proposed rules requiring tracking of a "lot or code number or other identifier of the food (to the extent this information exists)" are unclear insofar as the meaning of the phrase, "(to the extent this information exists)". Victory assumes that the rule requires that lot codes be traced through the food distribution system and records kept by lot code only if a food product contains a lot code on the outside of a shipper.

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[2] "Shipper(s)" as used herein means a corrugated shipping container and/or on the wrapper used to transport a retail package in bulk.

Frequently, shippers do not contain any lot code information, but the packages[3] do. In such a case, Victory assumes that distributors are not expected to open the shipper to record lot code information off the packages, and then reseal the shipper, but the rule is not clear on this point[4]. Many food manufacturers place a lot code on the outside of the shipper, but it is not done in a uniform way and distributors do not record this information. The impact of a proposed rule that would require lot number tracking in either event is staggering, and is described in detail below. Indeed it would involve marking and tracking individual shippers with separate and unique identifying information in warehouses that handle millions of shippers weekly.

To issue a truly effective lot-tracking requirement, two things would need to occur. First, FDA would need to require manufacturers to include lot code information on a shipper. Second, FDA would need to require manufacturers to do so in a standardized, machine-readable format (like a bar code or RFID tag) so that the then-existing technology could be utilized to collect the information in an economically reasonable manner. Indeed the most efficient tracking system would require a unique machine-readable code on every shipper produced. Until that time, however, it is premature to impose any requirement for lot number tracking.

Victory believes that the FDA should redirect its focus, away from how best to investigate incidents of food contamination *after* a problem has occurred, to proactively mandating measures that could reduce or prevent food from being exposed to adulteration in the first place[5] and to package their foods in tamper-evident packaging that would provide a means to consumers and stocking retailers to visually identify or detect possible adulteration. We believe that the FDA could do more to ensure food safety by mandating that all food products be contained in tamper-evident packaging, which, if breached or missing, would give consumers visible evidence that tampering has occurred and not by imposing a new layer of non-productive paperwork on all levels of the distribution channel for the sole purpose of expediting the FDA's tracing capabilities. This will add billions of dollars of new overhead into the food distribution system. The FDA assumes

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[3] "Package(s)" as used herein is defined in 15 U.S.C. §1459(b), and in general is the container or wrapping in which a consumer commodity is enclosed for use in delivery or display of that consumer commodity to retail purchasers, but does not include the shipper.

[4] We note that the opening of the shippers is not only contrary to industry practice (other than repackaging operations), but seems wholly inconsistent with the larger aim of the regulations and the legislation, which is to protect the integrity of a food product and its packaging.

[5] This could be achieved for example, by requiring manufacturers to keep better records regarding ingredients and to adhere to security enhanced good manufacturing practices ("GMPs" - see 21 CFR Part 110).

that the distribution industry will be able to pass the increased costs through to consumers (which would, in any event, result in higher prices to consumers). However, Victory believes that many of the FDA's assumptions are flawed and that small distributors will be forced to absorb the costs of compliance with the rule.

II. Current Federal Recordkeeping Requirements

Presently there are no laws or regulations that require food wholesalers to maintain records that identify a good from its immediate supplier to its immediate recipient or customer, by lot code or otherwise. Existing record keeping rules fall under either (i) GMPs, or (ii) recall guidelines set forth at 21 CFR Part 7.

GMPs for non-manufacturer food distributors generally fall under 21 CFR §110.93, which provides:

> **§110.93 Warehousing and distribution.**
>
> Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Under existing law, there is no reference to the types of records required to be kept by distributors such as the source or recipient of the food items it distributes, nor to or by lot codes.

The FDA's provisions for recall of food products[6] likewise do not require a distributor to maintain records of the goods it distributes from its immediate supplier to its immediate recipient. Those provisions provide in part (emphasis added):

> **§7.1 Scope.**
>
> ... This part also provides *guidance* for manufacturers and distributors to follow with respect to their *voluntary* removal or correction of marketed violative products (emphasis added).

[6] 21 CFR Subpart A.

§7.40 Recall policy.

... Recall is a *voluntary* action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the *voluntary* nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities.

§7.49 Recall communication.

(c) Contents. (1) A recall communication should be written in accordance with the following guidelines:
...
(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product . . .

In addition to the above, Section 7.56(b) of the recall regulations encourages companies to mark products by lot number. As the above provisions illustrate, the government does not presently mandate any specific comprehensive recordkeeping by food distributors. In the event of a problem with a product, the manufacturer will generally issue a notice to the trade. In cases where public health and safety are at risk, a notice is issued to the public. These notices generally contain information sufficient to allow the distributor to identify the affected product. Each distributor then checks its stock or inventory to see if it possesses the identified goods. If they do, they sequester the product and inform the manufacturer and/or authorities, and await instructions regarding disposition of the recalled product.

III. Records Typically Maintained by Food Distributors

Notwithstanding the fact that FDA currently imposes no record keeping requirements on food distributors, food distributors routinely keep records for business and tax reasons. The following is a summary of the types of records that Victory maintains and the manner in which we maintain them (this is important as it relates to the time it takes us to retrieve the records). We have cross referenced and coded the records which Victory presently maintains with the records proposed to be kept by distributors as set forth in §§1.337 and 1.345[7] to demonstrate how our current record keeping practices

[7] For purpose of this analysis, the following are the proposed requirements code: (a) the name, address, phone number, fax number and e-mail of the immediate previous and subsequent source/recipient; (b) a description of the brand name, variety and type of food; (c) the date we

would enable Victory to provide FDA with all of the information that it proposes to require, other than lot numbers.

Victory maintains its records in two formats, electronic and hard copy. Victory's electronic records consist of entries of key data entered into a computer system, including transaction dates, vendor/customer identification, invoice number, payment references, sales invoice number, and other typical accounting information. In addition, Victory's computer system contains information on Victory's purchases, sales, and inventory. Victory's electronic records would contain information (a), (b), (c) and (e) identified in footnote 7. The electronic records could be expeditiously provided to FDA within 4 hours as required by the proposed rule.

Victory concurrently maintains hard copy records throughout various Victory departments[8] in a large, 15,000 cubic foot warehouse, and on pallets in Victory's warehouses. These paper records consist of many millions of pieces of paper contained in hundreds of cardboard bankers boxes and filing cabinets. Victory estimates that paper "transaction" records, "transportation" records, "receiving" records and "pick or stage sheet" records for the two prior fiscal years plus the current fiscal accounting year are housed in approximately 410 cardboard bankers boxes and contain approximately 500,000 paper records. Victory's hard copy paper records contain information (a), (b), (c), (e) and (f) identified in footnote 7. Retrieval of paper records would take more than four hours since office personnel would have to manually locate requested records. Thus while Victory believes that it can also provide these hard-copy documents to the FDA, these voluminous documents, which are stored in different departments and storage facilities, would need to be hand-searched. Accordingly, Victory herein objects to that aspect of the proposed rule, which would require this type of information to be provided to FDA within 4 hours.

In summary, Victory knows, by product description, the type of food, brand name, variety and quantity where it purchased a given good and likewise where it sold the good. These records could be provided to the FDA and/or law enforcement authorities in a reasonably short time period. These records do not, however, identify an item by a lot code number or other unique identifier, nor does Victory tag or mark each case with a code or unique identifier such that Victory could track a particular shipper from an immediate supplier to an immediate customer. While Victory's records do not track lot numbers or otherwise identify, for each particular shipper or pallet of food

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received/released the food; (d) the lot code or other identifier of the food; (e) the quantity and pack configuration; and (f) the name, address, phone number, fax number and e-mail of the transporter.

[8] Accounting, logistics, transportation and inventory control.

shipped to a customer, the company from whom Victory received the shipper/pallet, Victory can nevertheless provide FDA with information sufficient to conduct a thorough tracing investigation. For any particular outgoing shipment, Victory can, using its records of incoming shipments, identify a small number of immediate previous sources from whom Victory may have received the specific goods contained in the outgoing shipment. Similarly, for any particular incoming shipment, Victory can, using its records of outgoing shipments, identify a small number of immediate subsequent recipients who may have received goods contained in the specific incoming shipment in question.

The proposed tracking lot numbers would involve a time consuming and expensive modification of the way Victory receives, stores and ships product, including the records generated in the process.

Victory believes that its record keeping practices are typical and representative of the records maintained by other food distributors and/or self-distributing retailers.

IV. How Foods Are Distributed in the United States

In the United States, food passes through many hands before it reaches consumers. Beginning with a manufacturer, a food item may travel to (i) a master distributor, (ii) a regional distributor, (iii) a co-operative distributor, (iv) a self-distributing retailer (such as large supermarket chains), (v) a food broker, (vi) a merchandiser and repackager, (vii) a mass merchandiser (such as a "mart"), (viii) an independent grocer, (ix) a self-distributing chain drug retailer (such as large chain drug stores), (x) an independent drug store, (xi) a convenience store, (xii) a specialty distributor, (xiii) an import/exporter, (xiv) a warehouse store, (xv) a specialty retailer, and/or (xvii) a department store. These are among some of the parties that regularly handle food items. Each time a good passes through a distributor, the item is transported by truck, rail, air or boat and goes through a number of cross-dock and warehouses before it reaches a consumer.

Food is often handled by repackagers or merchandisers, who may break larger quantity cases into smaller quantities to meet their customer's needs; create promotional packs or displays; create gift packs or warehouse club packs. These repackaging operations are integral to many companies' business strategies.

The complex food distribution model described above is a product of our nation's free enterprise, market-based economy. Each entity succeeds by filling a unique niche in the food distribution system. Businesses in the food industry include large publicly traded retailer chains to small mom and pop stores. Notwithstanding our complex food distribution model, the United States has the safest food products in the world.

As the FDA has acknowledged, safety is best achieved by controlling the environment where food is manufactured and packaged. At the same time, stocking retailers and consumers are in the best position to discover whether a food product has been tampered with. The "middlemen" in the distribution chain, i.e., distributors and transporters, do not open factory sealed shippers (except in the case of repackaging described above), never open retail packages (this would render them unsaleable), and do not handle or inspect individual shippers or packages. Distributors and transporters generally purchase, store and ship products in bulk cases/shippers in full truckload shipments. Thus the most efficient (and effective) way to assure safe food is to mandate tamper-evident packaging for food products similar to the FDA requirements for over-the-counter human drug products (21 CFR §211.132).

The FDA is wrong if it believes that the imposition of recordkeeping requirements can shield itself or the affected companies from unwarranted scrutiny and adverse publicity in a situation where either the FDA and/or the manufacturer has reason to believe that food is adultered and presents a threat to humans or animals. The FDA need only look at the tempest created when cyanide was found in Tylenol and grapes. Both the FDA and the manufacturer have affirmative legal duties to warn the public when a serious threat to food safety exists. Once the threat is made public, consumers will stop eating or using the affected product (e.g. grapes or Tylenol) for fear of injury. While the FDA may be sympathetic to a manufacturer's desire to avoid adverse publicity in the event of a threat to our food safety, publicity is the only way in which the FDA can reach all interested parties, especially the consuming public. Once the public has been informed, consumers will stop consuming, distributors and retailers will remove affected product from the system and law enforcement then can trace the source of the problem.

The cost of complying with the FDA's proposed rule will undoubtedly fall on the shoulders of small distributors and consumers. The food industry is highly competitive. Margins are extremely narrow at all stages of the industry from manufacturer to retailer. Accordingly, each stage of the food production and distribution system attempts to control its costs, and pass-on whatever costs it can to another level of the system. Not surprisingly, the larger players in this system have the greatest leverage to transfer costs from themselves to smaller players. The cost of complying with the FDA rule will be no exception.

The proposed FDA rule will impose a compliance cost which will pit large concerns against small concerns, and manufacturers against distributors and retailers. Each will try to pass the costs of the additional compliance requirements to the other. In

the end, small concerns and consumers will suffer.[9] The FDA's proposed solution to offset the acknowledged significant impact that the rule imposes on small businesses is to afford them additional compliance time. Under the express language of the Act, FDA was required to "take into account the size of a business in promulgating regulations under [Section 306]." This staggered compliance time concession to small businesses may look good on paper, but in reality, it is illusory. While the rule proposes that small concerns will have 12 to 18 months to comply, in the real world a small food businesses' suppliers and customers will dictate when and how it must comply. Victory, a small distributor under the rule, has already received requests from some of its large customers that it verify that it will be in compliance with the rule when it goes into effect for them. A distributor cannot partially comply because it has no idea where a good is headed when it purchases a food item for stock. Thus, FDA has failed to implement its statutory mandate to meaningfully consider the size of the business when promulgating its regulations.

Large companies, of the type that Victory and other small distributors do business with, regularly shift costs onto the smaller concerns – it's an unfortunate "cost of doing business". Because of competitive pressures, many of these costs cannot be passed through in the price of the goods, and must be absorbed by the small concerns. In other words the large concerns will "free ride" on the backs of the small concerns. Small concerns will be forced either to absorb the new costs or face the loss of business if they try to recoup the costs by raising the price of food products. The FDA seems to ignore the most basic reality of commerce: *consumers expect and demand lower prices*. In our present economy, can our country really afford the costs that the rule will impose?

One likely casualty of the proposed FDA rule is arbitrage, a practice that helps to deliver low-cost food to consumers. Most food manufacturers maintain multi-tiered pricing, selling identical goods at different prices in different market channels of trade or different geographic regions. The manufacturer's objective is to customize prices to exploit markets and maximize profits. However, these price differentials create an opportunity to arbitrage the goods. Through the practice of arbitrage, lower-priced goods move through the food distribution pipeline to regions where prices are higher. This occurs daily both intra-company and inter-company. For example, a national self-distributing grocery chain with 20 distribution facilities regularly moves goods purchased in one region at a lower price to one of its facilities in a region where the goods are available only at a higher price. That chain will buy a greater quantity than it needs to meet its requirements in the region where the product is available at the lower price, and

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[9] The FDA has acknowledged in the rule that prices will increase, but contends that consumers will be willing to pay higher food prices if it allows the FDA to trace the source of contamination more efficiently.

ship the product to a region where the chain's cost for the same item is higher. This kind of intra-company transfer is generally accounted for today via simple journal entries. However, under the proposed FDA rule, that company would be required to keep track of lot code information on the intra-company transfer. This will add a new and costly administrative burden to a common, everyday business practice. Price reducing arbitrage transactions also occur daily between unrelated companies (and even between competitors). However, if the cost to comply with the proposed FDA rule exceeds the marginal value obtained by a company as a result of an arbitrage transaction, the company will discontinue the practice. Food arbitrage is a line item on most food distributors and retailers financial statement. Eliminating arbitrage opportunities will cause substantial reductions in profits; will encourage layoffs and other expense reductions. At the same time, as the FDA has acknowledged, consumer prices will rise. In the end, the economy will suffer.

The FDA views the cost impact that its rule will have on various players in the food industry as an acceptable sacrifice, and believes that these compliance costs will be passed through to consumers because demand for food is inelastic. This will not be the case. The burdens and/or cost of complying with the FDA rule will be borne disproportionately by small food distributors.

V. How Food Distributors Receive, Store and Ship Products and the Related Records Generated

Like manufacturers, food distributors, self-distributing retailers and traditional retailers rely on multiple sources to supply food products to meet their business needs. It is a common practice for these concerns to commingle like food products from different sources in their warehouses and store shelves. Food products containing identical lot codes are distributed through multiple distributors (this occurs because a large manufacturing production may be contained in one lot code and orders from this large lot code batch are split into smaller orders and shipped to multiple destinations). When Victory purchases product, an order is entered into Victory's computer system. Information contained on a typical order is:

- Vendor name
- Purchase order number
- Date of purchase
- Date expected
- Payment information
- Number of shippers /dozens/packages ordered
- Shipper pack or configuration
- Description of the food, brand name, variety and shipper pack
- UPC (Uniform Product Code) of package

- Shipper/dozen/package price or cost

Victory enters this information into its computer system. Any other information about an order is generally handwritten on the order when it passes through Victory's logistics and transportation departments (such as a pick up location or special pick up instructions and name of the carrier and/or broker). Thus, some of the information that would be required by the FDA rule would be available electronically and is easily searchable and some is available only in paper form and would have to be searched manually (See above).

Once Victory places an order, the computer generates a paper "receiver report" which is a document that tells a warehouseman what goods were ordered and are expected on a truck and the expected delivery date. This information would typically include:

- Vendor name
- Pick-up date
- Expected delivery date
- Purchase order number
- Shipper or box number (this is a UPC box code – i.e. 10/ 12 oz or 12/ 10oz cans of peaches)
- Shipper/package (quantity in shipper and product size) ordered
- Item description
- Shipper ordered
- Pallet tie (shippers per pallet; i.e. number of shippers per row and number of rows on a pallet)
- Total shippers ordered

When the truck arrives, a warehouseman on a forklift removes the shippers from the trailer. In most cases, the goods are on pallets that may contain anywhere from a few shippers to a hundred or more. The warehouseman then records, by hand on the receiver sheet or report, the total number of pallets and shippers received for each ordered item. The warehouseman then compares that number with the information contained in Victory's receiver report. In most cases, the warehouseman determines the total number of shippers by counting one row of product and multiplying that number times the number of rows on a pallet and then multiplying the total shippers per pallet times the number of pallets. This procedure provides the total number of shippers on a trailer, and if this number matches the receiver report, no further count or shipper handling is done. Even in the event of count discrepancies, few shippers are actually handled to confirm shipper counts.

Following dock receipt, a warehouseman then places the shippers into Victory's warehouse. Victory uses a random slotting storage system, but tries to keep like goods together or in close proximity to each other. Again, Victory does not record any individual shipper or package information such as lot code.

Victory commingles goods in storage, regularly consolidating its inventory to efficiently use its warehouse space. Once commingled, it would be impossible for Victory, or any other food distributor, to ascertain where a particular shipper was sourced or sold.

Additionally, Victory daily transfers inventory between its six distribution facilities. These intracompany transfers are not recorded as separate transactions. Instead, a simple accounting journal entry is made noting that one facility's inventory has been decreased and another's increased.

When Victory receives an order from a customer, its computer system creates a "pick or stage" sheet. This document tells the warehouseman what goods to pick and stage for shipment to the customer. Victory picks goods, but does not record any individual shipper information such as lot code. In the case of food shipments, many transactions involve full pallets of shippers, thus the pallet/shippers are never broken down.

Victory transporters (common carriers) routinely make multiple pick up and delivery stops to pick up and/or deliver product. This complicates the record keeping process because goods may become commingled on a trailer outside of Victory's control (i.e. when a trailer is loaded and/or unloaded for safe load balance). In order to comply with the FDA rule, Victory would need to rely on the common carrier to record the required information and communicate it to Victory. Common carriers are typically small companies (under 50 trucks) and would have difficulty tracking case by lot code because many food facilities don't permit drivers on the docks or to inspect and count their loads. Drivers are paid by miles driven and are not compensated for time spent in obtaining data and recording information. Any additional record-keeping requirements imposed on carriers will result in a new burdens and costs that the carriers will pass through to the shippers (or the carriers profits will be diminished).

Notwithstanding the issues noted above, for any given food item for which a contamination issue arises, Victory can now reasonably ascertain its source and its customers. The FDA can use the information that Victory is currently able to provide to trace possible sources of contamination. Working through each source, the FDA can trace the path of the goods. In short, the proposed FDA rules really does not substantially enhance the FDA's enforcement capabilities or substantially reduce the time required to trace contaminated product back to its sources.

VI. The Impact of the Proposed Rule on a Small Food Distributor – The Cost of Compliance - - a Controlled Test

Victory conducted a controlled time study to ascertain the amount of time that it would take Victory to comply with the proposed rule, and the costs associated with that additional time. Based on our time study, if Victory were required to comply with the proposed rule it **would realize an 80% reduction in productivity.**[10]

Our study revealed the following information:

- The day we conducted our study we received 50 inbound trucks (48-53 foot trailers) and shipped 50 trucks outbound at one of our distribution facilities.

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[10] The anticipated new costs to Victory are not unique. Most distributors cannot track lot numbers. According to a study dated February 12, 2001, performed by Eastern Research Group, Inc. for the FDA captioned "Profile of the Prescription Drug Wholesaling Industry," it is estimated that only

> "10% of distributors can track products by lot number. The large majority of distributors must rely on the date of shipment information received from the manufacturer to determine when and whether they received the recalled materials. Using this information, wholesalers indicated that they can generally determine whether they still have the material and/or who among their customers might have received the product. Wholesalers store incoming products in their warehouses on shelves but, in most cases, do not track the flow of products through the warehouse on a lot-by-lot basis".... The wholesaler "cannot determine which of the customers (among those purchasing that product during the month) received the recalled lots." "Wholesalers reported that it was standard operating procedure to notify all customers of all recalls. Customers are then required to make their own checks to determine if they still have the recalled products and to notify their customers, as may be appropriate." at 1-29.

This report was prepared at the request of the FDA in connection with a review of the prescription drug wholesale industry. The prescription drug industry is FDA's most regulated category of wholesale distributors (see e.g., 21 CFR 205.4 (requiring pharmaceutical wholesalers to be licensed) and 21 CFR §205.50(f) (requiring records regarding the receipt and distribution of prescription drugs)). Since only 10% of pharmaceutical distributors are able to track products by lot number, it is not surprising that food distributors -- who are not subject to the extensive drug wholesale distribution regulations -- are not in a position to track food products by lot code from immediate sources to immediate recipients.

- On average a truckload contained goods from 2 different suppliers/customers.

- An average inbound truck contained 34 pallets, with 100 shippers per pallet (3,400 shippers received) with 8 different SKU's (stock keeping units). 33% of the pallets contained more than one item. A total of 170,000 shippers were received at the test facility on the test day.

- An average outbound truck contained 35 pallets, with 110 shippers per pallet (3,850 shippers shipped) with 20 different SKU's. 33% of the pallets contained more than one item. A total of 192,500 shippers were shipped from the test facility on the test day.

- It took Victory approximately 10 man-hours per truck to document the shippers from their immediate source to their immediate recipient. With our existing work force we would be able to handle only 20 trucks a day in a facility that daily handles 100 or more truckloads. This amounts to an 80% decrease in productivity. Put another way, Victory would have to increase its work force by approximately 500% to meet its existing business demands and comply with the proposed rule. This would equate to millions of dollars each year just for Victory.

- Victory handled 362,500 shippers at one distribution facility in one day. This equates to over 1,800,000 shippers a week from one facility. Using the hourly rate the FDA used in its calculations ($25.10), Victory's warehouse cost to track and record a shipper would be at least $.0692 per shipper (2 truckloads sampled = total of 7250 shippers; $25.10 x 20 extra man-hours = $502.00; $502.00/7250 = $.0692 per shipper). This translates into a daily increase in the expenses at one of Victory's warehouses of over $25,000. This would equate to adding an additional 125 new warehouseman at this facility to handle the new record keeping requirements.

- Victory's Computer department estimated that it would cost a minimum of $500,000 to upgrade our computer systems to handle lot code information. Presently, our system does not have a field or space for such information and to include this information would involve a system rewrite.

- Finally, Victory, and other small distributors, would incur additional expenses related to inputting the lot code data into its information system. Victory estimates that it would incur an additional expense of approximately $14,100 per day to enter approximately 363,500 lot codes

into a computer. We assumed 363,500 shippers handled each day and an average lot code of 15 digits. This equals 5,452,500 additional keystrokes per day of data entry. Assuming one data entry clerk could enter 9,700 keystrokes an hour (2.7 per second) and they are paid $25.10 an hour, the additional clerical data entry cost would be approximately $14,100 a day at one Victory facility. This would equate to adding 70 new data entry persons to handle the increased volume.

To summarize, Victory would have to add approximately 200 new employees at its test facility to meet the rule's tracking requirements. The annual cost to Victory at this facility would approximate $10,000,000 plus a $500,000 system change to comply with the rule. As a small business in a competitive industry, Victory would have trouble remaining a viable concern absent a mandatory requirement that these cost be passed through the system. If one were to assume that a shipper of food passes through at least three hands before reaching a store shelf, the cost to comply would easily reach in the billions per year[11].

VII. There Are Alternate Methods to Help Ensure Adequate Protection of the Nations Food Supply

- The FDA could mandate that each manufacturer who packages a food product for retail sale must package the food product in a tamper-evident package. The FDA already requires this for over-the-counter (OTC) human drug products (see 21 CFR §211.132). This should also be required for food products. That way, stocking retailers and consumers can visually determine whether a food item has been tampered with.

- The FDA should mandate that anti-tampering technology be incorporated into food product packaging. The FDA should set the standards and allow private enterprise to develop the technology-based solutions. Standards must not be capable of being manipulated by manufacturers to become a disguised method to control distribution of goods beyond the initial sale.[12]

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[11] The FDA has acknowledged in the rule that prices will increase but reasons that consumers would be willing to pay higher food prices if it allows the FDA to trace the source of contamination more efficiently. This self-serving analysis is only valid if the proper cost model has been developed and vetted so that true cost-risk comparisons can be made.

[12] The "first sale" doctrine holds that the right to control distribution of a product does not extend beyond the first sale of the product. *Sebastian Intern v. Long Drug Stores*, 53 F.3d 1073, 1074 (9th Cir. 1995); *Prestonettes v. Coty*, 264 U.S. 359 (1924), *Polymer Technology Corp. v. Mimren*, 37 F.3d 74, 78 (2d Cir. 1994); *Shell Oil Co. v. Commercial Petroleum, Inc.*, 928 F.2d 104, 107 (8th Cir. 1991).

Standards must consider the ease of application, cost, level of security, ease for industry and consumers to visually verify, resistance to duplication by "bad guys" and machine readability for inventory management and theft deterrence. The following are examples of possible anti-tampering technologies:

- **RFID or Auto-ID** – These are unique numbers embedded into individual smart tags or chips. These electronic product codes (EPC) can be read without human intervention. A smart EPC tag is integrated into the packaging material of the food product (shipper and/or package). An electronic signal is transmitted from that EPC tag. A distributor, transporter and retailer with an EPC reader communicate with the EPC via a radio signal and interpret the information and evaluate the information. This technology is several years away from every day use and allows all in the food distribution chain to use the EPC to track (1) product by lot code for recalls; (2) authenticate goods (anti-counterfeiting tool); (3) inventory management; and (4) control shrinkage. This technology does not require warehousemen or truckers to handle and inspect individual shippers in order to record information; it is transmitted electronically into the distributor/retailer's computer system without being touched.

- **Smart inks and dyes used in food products packaging**. There exist reliable, cost effective dyes and inks that could be used in food packaging material that would allow distributors, retailers and consumers to authenticate the goods.

- **Metal foil holograms incorporated into food product packaging material**. Holograms have been used for years by, among others, financial institutions and the recording industry for authentication purposes.

- **Security threads** incorporated into food product packaging material (similar to what the U.S. Treasury uses in our paper currency). Distributors, retailers and consumers could visually confirm the existence of a security thread in a package.

- **Digital watermarks** incorporated into food product packaging material. The same as security threads and inks.

- **Magnetic Stripes** like those used on credit cards and various other cards.

- Mandate that food businesses provide records to law enforcement of where they purchased a food product and who they sold it to within a reasonable time period, but not, without the aid of a machine readable technology incorporated into a shipper, by each shipper, from an immediate supplier to an immediate customer. The FDA will learn where a food item was purchased and where it was sold but not by specific lot code or shipper.

VIII. The Act Does Not Mandate The Records That FDA Proposes

All of these burdens would be imposed notwithstanding the fact that nothing in Section 306 (or the balance of the Act) mandates a requirement for the tracking of lot numbers as FDA proposes. Similarly, the Act does not require establishment and maintenance of records that track specific goods from an immediate previous source to an immediate subsequent recipient. Instead, the Act only provides:

> The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by person (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

Section 306(a).

The Act's reference to "records are needed by the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food" can be fully satisfied by records identifying the immediate previous sources of all incoming shipments and the immediate subsequent recipients of all outgoing shipments. In sum, the requirement to track lot numbers and any related requirement that distributors' records identify, for each particular shipper of food shipped to a customer, the company from whom the distributor received the shipper, and correspondingly for each particular shipper of food received by a distributor, the company to whom the distributor shipped the shipper, are not mandated by the Act, and FDA has full authority to omit these requirements from the final rule.

IX. Conclusion

The FDA has proposed a regulatory record-keeping scheme that imposes a huge burden and cost on the food distribution industry. The stated purpose is to make criminal investigations easier to conduct. However, the marginal benefit that may be gained in facilitating criminal investigations is more than offset by the burdens and costs to the regulated industry. Food distributors presently maintain records showing their food product suppliers and customers. This is sufficient information to permit law enforcement personnel to expeditiously and thoroughly find the source of contamination. It should be up to law enforcement to follow this trail to the source of an alleged crime. Historically, food manufacturers have been encouraged to keep records necessary to verify conformance with GMP and to enable recalls. Downstream distributors and retailers, and if necessary, consumers using information supplied by the manufacturers, such as lot code, inspect their goods to see if they possess any affected product, and if they do, then the affected goods are either set aside or passed back through the channel to the manufacturer for disposition. It is simply not credible for the FDA to assume that adverse publicity could be avoided in the case where the FDA has reason to believe that food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Preventative food safety should be the focus of the FDA's regulatory response to the Act, not law enforcement. Food safety is best controlled where food is manufactured and packaged. Stocking retailers and consumers are in the best position to discover whether food product has been tampered with. Tamper-evident packaging will best protect consumers. Since tamper-evident packaging occurs at the manufacturer level, the costs will pass through to the consumer because the first sale will include the cost and each vendor in the distribution chain will pass through these costs. The regulatory scheme the FDA proposes merely assumes these increased costs will be passed through, but as stated herein, many will be born by small distributors with out market power to pass them along the distribution chain.

Victory hopes that the FDA will carefully and thoughtfully consider our concerns and take them into account in crafting an appropriate rule that will protect consumers **and** preserve the food distribution system in our country without increasing its costs or otherwise imposing new recordkeeping burdens on our industry.

Very truly yours,

James R. Offic
Vice President and
General Counsel